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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Peter F. Whittington

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BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,741	Applicant(s) WHITINGTON, PETER F.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,5,19,21,29 and 32-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-18,20 and 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment filed on 6/30/08 has been entered.

Claims 1, 3, 6-18, 20, 22-28, 30-31 are present for examination.

Claims 2, 4-5, 19, 21, 29, 33-45 are withdrawn from non-elected Species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant recites that: "wherein the expandable, digestible member comprises meat" is confusing. Meat is digestible but not expandable. Examiner request Applicant provide the evidence that meat is able expandable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-18, 20, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman (EP 0218203, cited from IDS) in view of Ratjen et al. (US 5,603,950).

Berman discloses a delivery device comprising a catheter 14 or 20 having a first end and a second end. Since the string 14 has structure similar to a catheter such as flexible tube for insertion into a body cavity, therefore, the string 14 can be interpreted a catheter. An expandable, foam member 12

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connected to the first end of the catheter. Berman does not clearly disclose the foam member 12 is digestible. However, foam material can be digested but require times.

Meanwhile, Ratjen discloses an expandable, digestible sponge/foam filed in the gelatin capsule, col. 1, line 42-col. 3, line 46).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Berman with an expandable, digestible foam material, as taught by Ratjen, in order to absorb fluids, expandable and digestible when inserted into the stomach.

Regarding claim 9, Berman in view of Ratjen disclose the claimed invention except for the expandable, digestible member comprise a meat. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a meat (as meat is digestible foods), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claims 10-13, Berman in view of Ratjen disclose the claimed invention. Berman and Ratjen disclose an external diameter of the expandable, digestible member is collapsed or swelled state. Berman and Ratjen do not specifically disclose the percent of collapsible or swelling as listed in claims 10-13. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the percent of collapse or swelling, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 14-18, it is very well-known in the art to provide the catheter made of biocompatible thermoplastic polymer. The catheter must be flexible and rigid in certain degrees for easy inserting and manipulating the catheter into the body cavity.

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Regarding claim 20, it is noted that the product-by-process limitation “by a biocompatible adhesive” has not been given weight in determining the patentability of the device claim. See MEPE §2113.

Regarding claims 23 and 31, an erodable coating (gelatin) 18 surrounding at least a portion of the expandable, digestible member.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman in view of Ratjen et al. and further in view of Barr (US 6,514,487).

Berman in view of Ratjen disclose the claimed invention except for the erodable coating comprises a topical analgesic.

Barr discloses that topical analgesic useful for treating skin discomforts.

As we know that when the device is inserted into stomach, it will cause the patient uncomfortable and painful. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the topical analgesic in to the device of Potter in view Maniar, as taught by Barr for reducing the pains.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman in view of Ratjen et al. and further in view of Potter (US 4,781,704).

Berman in view of Ratjen disclose the claimed invention except for a connector connected to the second end of the catheter and wherein the connector comprises at least one port.

Potter discloses similarly device comprising: a connector 20 is connected to the second end of the catheter 15 and wherein the connector comprises a plurality of ports 21, 22; the connector is selected from Y-shaped connector; wherein ports 20-21 are female adapter.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide connector in to the device of Potter in view Maniar, as taught by Potter, to the user can introduce the drugs into the catheter.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 6-18, 20, 22-28, 30-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763